DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

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WARNING LETTER

NWE-02-02W

VIA FEDERAL EXPRESS

November 19, 2001

Richard Lamattina
President
Bay State Chowda Company
101 Phoenix Avenue
Lowell, MA 01852

Dear Mr. Lamattina:

We inspected your firm, located at 101 Phoenix Avenue, Lowell, MA, on July 25 through 30, 2001 and found that you have serious deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations, which were previously brought to your attention during previous inspections and letters, cause your seafood products to be in violation of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the seafood HACCP regulations through links in FDA's home page at www.fda.gov.

The deviations were as follows:

1. You must have a HACCP plan that lists the critical limits that must be met, to comply with 21 CFR 123.6(c)(3). However, your firm's HACCP plan for "Seafood Fully Cooked" lists a critical limit, "cook product to [redacted], at the cook stage critical control point that is not adequate to control pathogen survival including *Clostridium botulinum*. In addition, a critical limit for a pasteurizing cook consists of a time at a critical temperature as well as the critical temperature.

   Because pathogens may be reintroduced when ingredients are added, the cook time should begin when all ingredients have been added and the product has achieved a critical temperature. Table #A-4 of the *Fish & Fisheries Products Hazards & Controls Guidance: Third Edition* provides process times for a range of cooking temperatures to control the strains of *C. botulinum* that can grow at low temperatures (above 38°F).

2. You must have a HACCP plan that lists the critical control points, to comply with 21 CFR 123.6(c)(2). However, your firm's HACCP plan for "Seafood Fully Cooked" does not list the critical control point of "filling the product container" for controlling the food safety hazard of pathogen survival including *C. botulinum*. FDA recommends 185°F as a product temperature sufficient to control recontamination with pathogens during filling.

   It may also be prudent to use packaging that has been manufactured or treated to inactivate spores of *C. botulinum* that can grow at low temperatures (above 38°F).

3. You must have a HACCP plan that lists the critical control points, to comply with 21 CFR 123.6(c)(2). However, your firm's HACCP plan for "Seafood Fully Cooked" does not list the critical control point of "labeling" for controlling the food safety hazard of undeclared food allergens. For example, the label for NEW ENGLAND CLAM CHOWDA declares milk products, wheat flour and clams. The declaration of these allergens on labels is particularly important to sensitive individuals.

We may take further action if you do not promptly correct these above violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating. In addition, we may not provide certificates to your firm for export of your products to the European Union (EU) countries if you do not correct these deviations.

Please respond in writing within fifteen (15) days from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as your modified HACCP plan or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deficiencies.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

You may direct your reply to Karen N. Archdeacon, Compliance Officer, at the address noted above. If you have any questions concerning this matter, please contact Ms. Archdeacon at (781) 279-1675, Extension 1708.

Sincerely,

Gail T. Costello
District Director
New England District Office